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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,931	08/27/2003	Jong-Soo Woo	DE-1500	8064

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,931	WOO ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 6, 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed May 29, 2008 is acknowledged. Claims 1, 5, 6 and 8-10 remain under consideration, drawn to sustained-release compositions for oral administration comprising the drug nifedipine, a mixture of sodium alginate and xanthan gum, representing the carrier for sustained release of nifedipine, and a mixture of hydroxypropyl methylcellulose and propylene glycol alginate, representing the gel hydration accelerator.

Claims 1, 5, 6 and 8-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al., U.S. Patent 6,264,981, in view of Baichwal, A.R., U.S. Patent 5,846,563, in the last Office Action. It was asserted Zhang teaches sustained-release compositions for oral administration comprising nifedipine. See column 16, claims 22-24, where the dosage forms may be an oral transmucosal patch, a lozenge/troche, a lollipop or a chewing gum. See claim 28, where nifedipine is specifically disclosed as a pharmaceutical agent encompassed in Zhang's teaching. As required by instant claim 8, non-steroidal anti-inflammatory agents and antibiotics are further encompassed in Zhang's disclosure. See column 6, lines 51-53. Zhang teaches sodium alginate, xanthan gum, hydroxypropyl methylcellulose (HPMC) and propylene glycol alginate are ingredients that may be formulated with a drug for oral administration. Zhang provides a mechanism of controlling drug release by controlling dissolution and disintegration. Although a mixture of hydroxypropyl methylcellulose and propylene glycol alginate are characterized as "the gel hydration accelerator" and the mixture of sodium alginate and xanthan gum are characterized as "the carrier" in instant claims 1 and 10, these four compounds are characterized by Zhang as "dissolution

agents." Baichwal teaches a combination of a gelling agent and an inert diluent, i.e., a mixture of xanthan gum and locust bean gum, with or without a cross-linking agent and hydrophilic polymer, i.e., hydroxypropylmethylcellulose, provides a product to which the desired active medicament (nifedipine) is physically admixed. See column 8, lines 19-27. The bioavailability of nifedipine, a poorly soluble drug, is thus increased. The open language of the present claims allows for the inclusion of any number of additional active or inactive agents.

While conceding the four components of the present invention, i.e., HPMC, propylene glycol alginate, sodium alginate and xanthan gum, are included in Zhang's teaching, Applicants argue Zhang is directed to an oral transmucosal delivery system. Further, although Applicants concede Baichwal is directed to a sustained release formulation, Applicants urge the formulation of Baichwal fails to use a hydrophilic polymer and the formulation of Baichwal fails to release the drug at a constant rate following zero order kinetics for 24 hours or more.

> Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record under 35 U.S.C. 103 is maintained for the reasons of record. The prior art of record teaches oral, sustained-release compositions, as tablets, comprising nifedipine wherein the four required components of the composition are included. Gelling agents such as alginates and hydroxypropylmethylcellulose are well known in the art. The present claims do not require a demonstration of zero order kinetics. Baichwal teaches the ratio of medicament to gelling agent is preferably about 1:3 to about 1:8 (column 2,

lines 58-60) and the ratio of inert diluent (carrier) to gelling agent is about 1:8 to about 8:1). Dosages of nifedipine are disclosed to be 20 mg, 30 mg, 60 mg and 90 mg (column 6, lines 66-67). The components are physically admixed.

Baichwal further teaches a ratio of xanthan gum to locust bean gum to be about 1:1. See column 4, line 49, to column 5, line 2, as required by instant claim 6.

Vellekoop et al., U.S. Patent 4,765,984, teaches a ratio of sodium alginate to gum is about 1:1.6 to 2:1, as required by instant claims 1 and 10. See claim 10, column 12. Bowersock et al., U.S. Patent 6,656,470, teaches a preferred weight ratio of a cellulose ether to an alginate to be about 1:1 about 1:5. (Both Vellekoop and Bowersock are provided only as evidence and are not presented as a new rejection under 35 U.S.C. 103.)

Thus the currently claimed specific proportions of the claimed ingredients are not seen to be inconsistent with the ratios that would have been determined by the skilled artisan in formulation chemistry through no more than routine experimentation. Ample guidance is provided. It is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

No claim is allowed.

THIS ACTION IS MADE **FINAL**. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 30, 2008

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614